Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested. Claims 1, 8 and 13 are amended, and claims 2, 4-6, 9, 11-12 and 14-22 are canceled without prejudice or disclaimer. Thus, the pending claims are claims 1, 3, 7-8, 10 and 13.

In response to the Examiner's assertion in the Advisory Action that the term "outwardly" is not defined, Applicants respectfully request that the Examiner consider Applicants' specification. The present specification discloses a cannula having apertures that are "buckle resistant," *i.e.*, the apertures of the cannula are designed so that the individual apertures do not pucker outward when the cannula body is flexed or bent, *e.g.*, when inserted into a desired location, such as the inferior vena cava or right atrium in a patient's body (paragraph 6 in the specification as filed). By way of comparison, Applicants disclose in FIGs. 1-2 an exemplary conventional cannula that illustrates the phenomenon of "aperture buckling" (paragraph 7 in specification as filed). In particular, when the conventional cannula is bent, sides 3 and 4 of individual aperture 5 on the concave side 8 are pushed toward one another and the aperture 5 buckles outward at other sides 6 and 7 (*Id.*). Applicants further disclose that when an aperture buckles outward in such a manner, a scoop is created that extends outward from the cannula wall, which may damage the sides of a vessel wall in the patient (paragraph 8 in specification as filed). Thus, it is respectfully submitted that the term "outwardly" within the context of the phrase "such that the corners do not buckle outwardly as the cannula is flexed" is clear. Moreover, Applicants submit it is also clear to which spatial directed the term 'outward' is referring and that the claims and specification are in compliance with 35 U.S.C. § 112.

Regarding claim 8, the Examiner is respectfully requested to consider MPEP 2173.05(g). In particular, "a functional limitation is an attempt to define something by what it does, rather than by what it is (*e.g.*, as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an

invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

The 35 U.S.C. § 103(a) rejection of the claims

Claims 1, 3, 6-8, 10 and 12-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ash *et al.* (U.S. Patent No. 5,947,953) in view of de la Rama *et al.* (U.S. Patent No. 6,246,914). The cancellation of claim 6 and 12 renders this rejection of claims 6-12 moot, and as this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the framework for the objective analysis of determining obviousness under 35 U.S.C. § 103(a) is stated in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The factual analysis involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, and (3) resolving the level of ordinary skill in the pertinent art. Obviousness requires a suggestion of all limitations in a claim. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F. 2d 981, 985 (CCPA 1974). Applicants respectfully submit that in rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with new evidence or argument shift to the applicant. *In re Rijckaert*, 9 F. 3d 1531, 1532 (Fed. Cir. 1993) (citations omitted).

As amended, claim 1, upon which claim 3 and 7 depend, is directed to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the

wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures have first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen, and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen. Claim 8, as amended and upon which claims 10 and 13 depend, is directed to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed, and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen.

In particular, the Examiner alleges that it would have been obvious to the art worker to modify the device of Ash *et al.* with the "aperatures shaped in an eye-like fashion" of de la Rama *et al.* "to ensure … fluid … flow though the apertures even when the catheter … buckles" (page 4 of the final Office Action).

Ash *et al.* disclose a hemodialysis catheter assembly that is split into two separate lumens, each having holes located on its distal end (abstract; column 7, lines 27-29; column 9, lines 62-65; column 11, lines 22-27; FIGs. 5 and 7). The Examiner's attention is directed to column 7, lines 35-39 of Ash *et al.*, wherein it is disclosed that the lumen, not the aperture shapes as asserted by the Examiner at page 4 of the final Office Action,

can be configured to have an oval, circular, elliptical, square, triangular or kidney-bean cross-sectional shape. However, Ash *et al.* do not disclose or suggest a venous cannula, let alone one having *inter alia* apertures having first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen , and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen. Nor do Ash *et al.* disclose or suggest a venous cannula having *inter alia* apertures that include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed, and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen. Therefore, Ash *et al.* do not render the pending claims obvious.

de la Rama *et al.* do not remedy the deficiencies of Ash *et al.* de la Rama *et al.* disclose a high torque radiofrequency ablation catheter having a slit tubular element with either a plurality of slits, for example, a perpendicular slit, an angled slit, a curved slit, or a random slit, or having at least one continuously spiraling slit (abstract, FIG. 1; column 3, lines 12-19; lines 23-36; column 5, lines 60-61). As defined by de la Rama *et al.*, the "slits" cut into the device are "straight or curved narrow cut[s] or opening[s]" (column 2, lines 65-67). As disclosed by de la Rama *et al.*, the slit tubular element may be made from polypropylene, polysulfone, platinum, stainless steel, Nitinol, gold, silver, iridium and/or tungsten (column 6, line 66-column 7, line 3).

However, de la Rama *et al.* do not disclose or suggest a venous cannula. Even assuming, for the sake of argument, that Figure 3 of de la Rama *et al.* discloses "eye-shaped slits which have a first and second corners defined by arcuate portions that intersect with each other with the spatial arrangement of the major and minor axes meeting the limitations of the claimed invention" as asserted by the Examiner in the Advisory Action is correct, which it is not, Applicants respectfully submit there is no

disclosure or suggestion in de la Rama *et al.* of a venous cannula comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures have first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen, and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen, or of a venous cannula comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed, and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen. Therefore, the pending claims are not obvious in view of de la Rama *et al.*

Applicants' respectfully submit that *prima facie* obviousness has not been established. As discussed above, neither Ash *et al.* nor de la Rama *et al.* disclose or suggest all of the limitations of the pending claims. The Examiner concedes at page 3 of the final Office Action that Ash *et al.* do not disclose the claimed aperture. The

Examiner is urged to consider that any disclosure in Figure 3 of de la Rama *et al.* is limited to the disposition of de la Rama *et al.*'s "straight or curved narrow cut[s] or opening[s]" when the ablation catheter is flexed ("at a bending state") (column 2, lines 65-67; column 6, lines 10-17). As evidence that de la Rama *et al.*'s slits are not designed to retain the shape shown in figure 3, the Examiner's attention is directed to figure 4 of de la Rama *et al.*, which discloses the disposition of the slits while in a non-bending state. As can be seen, slit 13 of the device is neither eye-shaped nor open.

The Examiner alleges in the Advisory Action that the corners of the slits in the de la Rama *et al.* ablation catheter would not buckle outwardly with "at least some flexing" of the ablation catheter. It is respectfully submitted that rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In re Kahn, 441 F. 3d 977, 988 (Fed. Cir. 2006). As conceded by the Examiner, de la Rama is silent as to whether or not the slits would in fact buckle outwardly when flexed. Applicants' submit that given the list of materials disclosed by de la Rama *et al.* to be useful in the manufacture of the ablation catheter, *i.e.*, materials that confer torque transmissibility to the de la Rama *et al.* ablation catheter, *e.g.*, polypropylene, polysulfone, platinum, stainless steel, Nitinol, gold, silver, iridium and/or tungsten, de la Rama *et al.* do not clearly disclose or suggest apertures that do not buckle outwardly as the cannula is flexed. Thus, there is no disclosure or suggestion in de la Rama *et al.* of apertures that do not buckle outwardly as the ablation catheter is flexed. Hence, the pending claims can not be rendered obvious by de la Rama *et al.*

Applicants' respectfully submit that the art worker would not be motivated to modify the holes of Ash *et al.* with the slits of de la Rama *et al.* as suggested by the Examiner, and would not have a reasonable expectation that such catheter would be successful for perfusion. The Examiner is respectfully requested to consider that such a modification would render the Ash *et al.* catheter unsatisfactory for its intended purpose, *i.e.*, replacing the holes at the distal end of the Ash *et al.* catheter with the slits of de la

Rama *et al.* would limit the efficacy of the hemodialysis catheter depending upon its state of flex, *i.e.*, the catheter slits would open (or not) during a dialysis procedure depending upon the bending state of the catheter, and/or potentially pinch sensitive tissue in the slits while flexed causing injury to the patient. See M.P.E.P. 2143.01(V).

Furthermore, given the disclosure by de la Rama *et al.* to include perpendicular slits, angled slits, curved slits, and/or random slits in the ablation catheter actually *teaches away* from apertures having any particular shape, let alone apertures having "first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen" or the "eye-shaped" apertures as presently claimed.

Therefore, for the reasons discussed above, it is respectfully submitted that the pending claims are not *prima facie* obvious over Ash *et al.* in view of de la Rama *et al.* Withdrawal of the 35 U.S.C. §103(a) rejection of the claims is thus proper and respectfully requested.

Claims 7 and 13 are independently patentable

As discussed above, neither Ash *et al.* nor de la Rama *et al.* disclose or suggest Applicants' venous cannula as claimed. As discussed above, Ash *et al.* disclose that the location of the hemodialysis catheter holes is limited to the distal end of the device. In particular, Ash *et al.* disclose that the holes are arranged "helically and circumferentially around the distal end regions" of the device (column 11, lines 29-34). de la Rama *et al.*, as discussed above, disclose that their ablation catheter may have either one continuous spiral slit (see FIGs. 6-7) or a plurality of slits (FIGs. 2-5). Regarding the location of the latter, de la Rama *et al.* disclose that the plurality of slits may be on the "same side, on the opposite side, or randomly on the surface of the split tubular element" (column 6, lines 5-7). Given the foregoing, it is respectfully submitted that both Ash *et al.* and de la

Rama *et al.* actually *teach away* from apertures that are "arranged into a plurality of rows generally extending along the longitudinal axis of the lumen" and apertures that are "evenly distributed on the body . . . offset such that the apertures in the adjacent rows are different distances from a distal tip of the body" as claimed in the present invention. Thus, it is respectfully submitted that claims 7 and 13 are patentable over the cited art, and notice of their allowance is respectfully requested.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to telephone Applicants' Representative at 763-505-8423 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

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